IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

REX J. KURIGER		Group Art Unit:	3736
Serial No.:	10/590,531	Examiner:	Adam J. Eiseman
Filed:	August 24, 2006	Confirmation No.:	9794
Docket No.:	MSE-2685 / 247082-000090USPX		
For:	**METHOD AND APPARATUS FOR MEASURING AN ANALYTE IN A BODY FLUID**		

APPEAL BRIEF UNDER 35 U.S.C. 134

MAIL STOP APPEAL BRIEF – PATENTS (VIA EFS)
COMMISSIONER FOR PATENTS
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the final rejection of claims set forth in the Office Action of May 25, 2010, a Notice of Appeal was filed on July 14, 2010, pursuant to 37 C.F.R. § 41.31, concurrent with the corresponding fee set forth in 37 C.F.R. § 41.20(b)(1). In support of the Notice of Appeal, Appellant now submits the following Appeal Brief and corresponding fees pursuant to 35 U.S.C. § 134 and 37 C.F.R. §§ 41.37, 41.20(b)(2). In compliance with 37 C.F.R. § 41.37(a)(1), this Appeal Brief is being timely filed within two months from the filing of the Notice of Appeal.

To the extent necessary, please charge any shortage in fees due in connection with the filing of this brief, including extension of time fees, to Nixon Peabody, P.C. Deposit Account No. 50-4181, Order No. 247082-000090USPX, and please credit any overcharges and additional fees to the same deposit account.

I. REAL PARTY IN INTEREST

The real party in interest is Bayer HealthCare LLC, the assignee of record, which is a corporation organized and existing under the laws of the State of Delaware.

II. RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals, interferences, or judicial proceedings related to this appeal.

III. STATUS OF CLAIMS

Claims 1-34 were originally presented in this application. Claims 8 and 9 have since been cancelled, without prejudice or disclaimer. *See* Appellant's Preliminary Amendment, entered August 24, 2006. Claim 35 was subsequently added in Appellant's "Amendment & Response to Office Action dated October 8, 2008," which was entered on January 12, 2009. Claims 1-7 and 10-35 therefore remain pending. No claims have been allowed. Claims 1-7 and 10-35 have each been rejected two times, and are therefore the subject of this appeal.

IV. STATUS OF AMENDMENTS

There have been no amendments to the claims, specification, or drawings filed subsequent to the Final Office Action, mailed on May 25, 2010 ("Final Office Action"). The claims under appeal were previously presented in Appellant's "Response under 37 C.F.R. § 1.111," which was entered on February 19, 2010 ("February 2010 Response"). A listing of the claims on appeal is provided in the attached Appendices. *See*, *infra* § IX, Claims on Appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellant's invention relates generally to testing systems for determining the concentration of an analyte in a fluid sample, and more particularly to systems for lancing a test subject's skin and harvesting a body fluid sample for determining the concentration of an analyte in the fluid sample. Independent claim 1 is directed to an apparatus for lancing the skin of a test subject and collecting a body fluid sample from the lanced site. Independent claim 12 is directed

to a method for lancing the skin of a test subject and collecting a body fluid sample from the lanced site for determining the concentration of an analyte in the fluid sample. Independent claims 1 and 12, and all claims respectively depending therefrom, are the subject of this appeal.

Please note, all paragraphs and line numbers indicated below are designated with respect to the subject specification as published in U.S. Patent Application Publ. No. 2007/0213636 A1. To that extent, much of the description set forth below is made with respect to the various representative embodiments depicted and described in the subject specification and accompanying drawings. These descriptive comparisons and exemplifications are made purely for explanatory purposes in compliance with 37 C.F.R. § 41.37(c)(1)(v), and are therefore not intended to be limiting and should not be construed as limiting.

A. INDEPENDENT CLAIM 1

Claim 1 is directed to "[an] apparatus for lancing the skin of a test subject [and] collecting a body fluid sample from the lanced site on the skin of the test subject". One such lancing apparatus is presented in an exemplary embodiment at 10 in FIGS. 1-4 of the drawings, and discussed with some particularity in paragraphs [0015] through [0025] of the specification. The apparatus of claim 1 includes "a body having an open end," *see, e.g.,* FIG. 1 (body 12, forward end 34 through which lancet 18 passes); ¶ [0015], Ln. 6-8, and "a hollow lancet" with "a tip adapted to puncture skin and to collect a body fluid sample," *see, e.g.,* FIG. 1 (lancet 18); ¶¶ [0017], Ln. 4-5 and 8-10, [0018], Ln. 7-10. "[T]he interior of the hollow lancet form[s] a channel for moving a fluid sample from the tip to a reaction area". *See* ¶¶ [0006], Ln. 5-8, [0017], Ln. 4-5, [0025], Ln. 4-10.

The apparatus of claim 1 further comprises "a lancing mechanism disposed within the body [and] coupled to the lancet at an end of the lancet opposite the tip". *See, e.g.,* FIG. 1 (lancing mechanism 16); ¶ [0015], Ln. 6-8 and 13-16. The lancing mechanism "[is] adapted to move the lancet between a retracted position," (FIG. 2), "a lancing position for puncturing the skin of a test subject," (FIG. 3), "and a collection position for collecting the body fluid sample," (FIG. 4). *See, e.g.,* ¶¶ [0009]-[0011], [0022], Ln. 4-14, [0025], Ln. 5-8. "[A]n outer end cap [has] a first end coupled to the open end of the body and a second end for contacting the skin of the test subject". *See,* FIGS. 1 and 2 (outer end cap 30); ¶ [0016], Ln. 1-3, 5-6 and 13-15. The

outer end cap of claim 1 "form[s] a first aperture therein that the tip of the lancet enters when in the lancing position, the outer end cap having a wall extending to the second end thereof". *See, e.g.,* FIG. 2-3 (open end 36, annular wall of outer end cap 30 shown in cross-section); ¶¶ [0016], Ln. 9-12, [0022], Ln. 1-4.

Independent claim 1 also recites "an inner end cap [that is] disposed within the outer end cap". *See* FIG. 1 (inner end cap 32); ¶ [0016], Ln. 1-5. The inner end cap of claim 1 "[has] a first end coupled to the open end of the body and a second end forming a second aperture therein that the tip of the lancet enters when in the lancing position". *See* (open end 38); ¶ [0016], Ln. 1-5 and 9-15, [0022], Ln. 4-9. The second end of the inner end cap "[is] adapted to contact the skin of the test subject when the lancet is in the collecting position, the inner end cap having a wall extending to the second end thereof". *See* FIG. 4 (annular wall of inner end cap 32 shown in cross-section); ¶¶ [0016], Ln. 5-9, [0024], Ln. 4-7. "[T]he wall of the outer end cap extend[s] farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap". *See, e.g.,* FIGS. 2-4; ¶ [0024], Ln. 1-7. The second end of the outer end cap and the second end of the inner end cap "remain in contact with the skin in the lancing position to assist in sample formation and collection." *See, e.g.,* FIGS. 3 and 4; ¶¶ [0023], Ln. 4-9, [0024], Ln. 1-10.

B. INDEPENDENT CLAIM 12

Claim 12 is directed to "[a] method for lancing the skin of a test subject and collecting a body fluid sample from the lanced site on the skin of the test subject for determining the concentration of an analyte in the body fluid sample with a lancing and collection device". *See* ¶ [0072], Ln. 1-3. Various lancing and collection devices by which the present method may be practiced are illustrated in exemplary embodiments in FIGS. 1-6 of the drawings, and discussed with some particularity in paragraphs [0015] through [0030] of the specification. The lancing and collection device "includ[es] a hollow lancet having a tip for puncturing skin". *See, e.g.,* FIG. 1 (lancet 18); ¶¶ [0017], Ln. 4-5 and 8-10, [0018], Ln. 7-10. The method of claim 12 comprises, *inter alia*, "placing an outer end cap of the device against the skin of a test subject," and "puncturing the skin with the lancet in a lancing position". *See, e.g.,* FIGS. 2 and 3 (outer end cap 30, skin S); ¶ [0022], Ln. 1-11.

Claim 12 also recites "positioning the punctured skin against an edge of an inner end cap of the device, the inner end cap being disposed within the outer end cap". *See, e.g.,* FIGS. 3 and 4 (inner end cap 32, skin S); ¶¶ [0016], Ln. 1-5, [0024], Ln. 1-7. The method of claim 12 further comprises "disposing the tip of the lancet a predetermined distance from the skin pulled against the edge of the inner end cap," and "collecting the body fluid sample from the puncture skin with the tip of the lancet in a collection position". *See, e.g.,* FIG. 4 (collection position); ¶ [0011]. For example, paragraph [0025] explains that, after the hollow lancet 18 punctures the test subject's skin S, a fluid sample B (e.g., blood pool) forms on the skin S at the puncture site. *See, id.,* Ln. 1-3. The lancing mechanism 16 holds the skin under vacuum (e.g., via diaphragm or bellows that displaces air within the lancing device 10), and locates the hollow tip 40 of the lancet 18 in a collection position adjacent the lance site for collecting the body fluid sample B. *See ¶¶* [0023], Ln. 9-11, [0025], Ln. 5-8. The sample B contacts the hollow lancet 18, and is drawn into the lancet 18 via capillary action. *See ¶* [0025], Ln. 8-10. "[T]he outer end cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection." *See, e.g.,* FIGS. 3 and 4; ¶¶ [0023], Ln. 4-9, [0024], Ln. 1-10.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-7 and 10-35 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,951,492, to Douglas et al. ("Douglas"), in view of U.S. Patent Application Publ. No. 2003/0171696 A1, to Dosmann ("Dosmann"), and U.S. Patent Application Publ. No. 2004/0127818 A1, to Roe et al. ("Roe").

VII. ARGUMENTS

A. LEGAL SUMMARY - 35 U.S.C. 103

A proper rejection under Section 103(a) of the U.S. Patent Act requires the examiner establish *prima facie* obviousness. The legal concept of *prima facie* obviousness is a procedural tool of examination, allocating who has the burden of going forward with production of evidence in each step of the examination process. *See* MPEP 2142. *See, also, In re Rinehart*, 531 F.2d 1048 (CCPA 1976); *In re Linter*, 458 F.2d 1013 (CCPA 1972). Of notable importance,

"[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." MPEP § 2142 (emphasis in original). *See, also,* MPEP 2106 (The burden is initially on the USPTO to set forth a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Consequently, "**[i]f the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness**." MPEP § 2142 (Italicized emphasis in original; bold emphasis added). *See In re Piasecki*, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

To properly substantiate a *prima facie* case of obviousness under § 103(a) requires, *inter alia,* **the applied references must teach, suggest, or otherwise disclose each and every element and limitation of the rejected claims**. *See Ex parte Wada and Murphy,* Appeal No. 2007-3733, Slip Op. at 7 (BPAI January 14, 2008) ("Obviousness requires a suggestion of all limitations in a claim." *Citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).); *In re Kotzab*, 217 F.3d 1365, 1369-71 (Fed. Cir. 2000); *In re Royka*, 490 F.2d 981 (CCPA 1974) ("[O]bviousness requires a suggestion of all limitations in a claim.") In setting forth a *prima facie* case, the examiner may not opportunely disregard certain claim terms; rather, "[every] word[] in a claim must be considered in judging the patentability of a claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). In effect, "[w]hen determining whether a claim is obvious, **an examiner must make 'a searching comparison of the claimed invention - including all its limitations - with the teaching of the prior art**.'" *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added).

In addition to demonstrating that the applied art teaches every element and limitation of a rejected claim, **the law of obviousness also requires the reviewing examiner to clearly articulate "an apparent reason" why a person skilled in the art would be compelled to combine "the known elements" to achieve the invention claimed**. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added). *See, also*, MPEP 2143 ("The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.") "[R]ejections on obviousness **cannot be sustained with mere conclusory statements**; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added). To that extent, the mere fact that references can be combined or modified does not render the resultant combination obvious. *See*

MPEP 2143.01 (III).

The Supreme Court has clarified that **"a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."** *KSR Int'l*, 127 S. Ct. at 1741 (emphasis added). The Federal Circuit has acknowledged that "[m]ost if not all inventions arise from a combination of old elements." *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000). *See, also, In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir. 1998). In light of this fact, piecemeal identification in the prior art of each individual part claimed "is insufficient to defeat patentability of the whole claimed invention". *See Kotzab*, 217 F.3d at 1369. *See, also, In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998). Rather, **there must be "an apparent reason" in the prior art "to combine the known elements in the fashion claimed by the [applicant]"**. *KSR Int'l*, 127 S. Ct. at 1742 (emphasis added).

Section 2143.01(VI) of the MPEP notes that **an examiner's proposed modification of a cited reference is not sufficient to render a claim prima facie obvious "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified".** Citing *In re Ratti*, 270 F.2d 810 (CCPA 1959). The court in *Ratti* emphasized that a proposed modification which "change[s] the basic principle under which the [primary reference's] construction was designed to operate" is grounds for overturning a finding of obviousness. *See, also*, MPEP 2143.01(VI) and 2145(III).

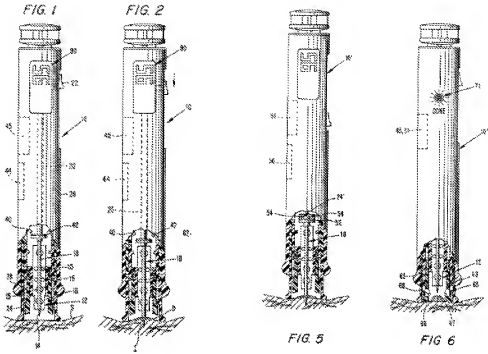
In determining the differences between the prior art and the claims, the question under § 103(a) "is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP 2141.02, citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983). The Federal Courts have historically and consistently made clear that a claimed invention cannot be statutorily "obvious" where the prior art teaches away from the claimed invention. *See e.g., In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001). It is therefore axiomatic that each reference be considered in its entirety, especially portions that teach away from an applicant's claimed invention. *See* MPEP § 2141.02; *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.3d 1540, 1550-51 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). A prior art reference may be considered to "teach away" when "a person of ordinary

skill, upon reading the reference ... would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). *See, also, Monarch Knitting Mach. v. Sulzer Morat GmBH*, 139 F.3d 877, 885 (Fed. Cir. 1998). Of paramount significance, in the case of *In re Gurley*, the Federal Circuit unequivocally held "that **references that teach away cannot serve to create a *prima facie* case of obviousness**." 27 F.3d 551, 553 (Fed. Cir. 1994), citing *In re Sponnoble*, 405 F.2d 578, 587 (CCPA 1969) (emphasis added). The pending § 103(a) rejection is improper for at least four reasons: first, there is no teaching or suggestion to combine Douglas and Dosmann; second, Douglas explicitly teaches away from the Examiner's proposed modifications; third, the Examiner's proposed modifications would change the principle of operation of the Douglas reference.

For at least the reasons stated below, Appellant respectfully submits that the Examiner has not set forth a *prima facie* case of obviousness under 35 U.S.C. § 103.

B. THE § 103(A) REJECTIONS OF CLAIMS 1-7 AND 10-35 ARE FACTUALLY ERRONEOUS AND LEGALLY IMPROPER

Claims 1-7 and 10-35 are rejected under 35 U.S.C. § 103(a) as being obvious over Douglas, in view of Dosmann and Roe. Douglas discloses a lancing apparatus 10 for sampling body fluid. *See* Douglas Abstract; Col. 1, Ln. 29-31. The lancing apparatus 10 includes a disposable lancet 12 with a skin-lancing needle 14, a capillary tube 18 for collecting the body fluid, and a housing 26, as seen in FIG. 1 (recreated below). *See, id.,* Col. 5, Ln. 25-46. A pusher 20 is displaceable via an actuator knob 22 to the thereby move the lancet 12 from a retracted position (FIG. 1) to a lancing position (FIG. 2, recreated below), and for moving the capillary tube 18 to the lancing site for collecting body fluid. *See, id.,* Ln. 37-43 and 59-64. Douglas' disposable lancet 12 is telescopes within a cylindrical stimulator sleeve 24, which is longitudinally slidable relative to the housing 26. *See, id.,* Ln. 44-46. An inner sleeve (shown in FIGS. 1 and 2, but labeled only in FIG. 6 at 66) is operatively coupled to the housing 26 and disposed within the outer end cap 24. *E.g., id.*, Col. 7, Ln. 31-35.



The Final Office Action acknowledges that Douglas does not disclose (1) a hollow lancet; (2) an interior capillary channel of the lancet for moving the fluid sample from the tip to a reaction area; (3) a lancing mechanism providing a collecting position; and (4) the outer end cap and the inner end cap remaining in contact with the skin when in the lancing position to assist in sample formation and collection. *See* Final Office Action, Item No. 3, at 3. Dosmann is thus applied for teaching an optical format 10 (FIG. 1) with a hollow lance 12, the interior of which forms a channel 13 for moving a fluid sample from the sharp tip 16 to a reaction area. *See id.*, at 3-4. *See, also,* Dosmann, FIGS. 1 and 2; ¶¶ [0010] and [0011]. Roe is applied for allegedly teaching an inner end cap 82 disposed within an outer end cap 46 (FIG. 2), where the outer and inner end caps 46, 82 remain in contact with the skin when in the lancing position to assist in sample formation and collection. *See* Final Office Action, at 4. From these teachings, the Examiner concludes that it would have been obvious to substitute Douglas' disposable lancet (i.e., needle 12, capillary tube 18, and test element 30) with Dosmann's hollow lancet 10, and to modify Douglas' stimulator sleeve 24 and inner sleeve 66 to both remain in contact with the skin during the lancing position as taught by Roe.

The pending § 103(a) rejections are improper for at least three reasons: first, Douglas explicitly teaches away from the Examiner's proposed modifications; second, there is

no teaching or suggestion to combine Douglas and Dosmann; and, third, the Examiner's proposed modifications would change the principle of operation of Douglas. Each of the foregoing reasons will be individually discussed in detail below.

1. Douglas explicitly teaches away from the proposed modifications.

Douglas teaches away from the Examiner's proposition to modify the stimulator sleeve 24 and inner sleeve 66 to both remain in contact with the patient's skin during lancing, as taught by Roe. Douglas teaches that the drop sensing mechanism 65 (FIG. 6), which is mounted on the inside perimeter of the inner sleeve 66, is used to determine whether a drop of body fluid expressed from an incision is of sufficient size to provide a proper sample. *See* Douglas, Col. 7, Ln. 29-35. The drop sensing mechanism comprises a pair of diametrically opposed electrodes 67, 68 that are connected by wires 69 to a battery 45 or 51. *See, id.*, Ln. 35-36. The electrodes 67, 68 are "positioned such that **when the outer sleeve 24 is retracted** in response to a pressing down of the housing," the electrodes will contact the drop of body fluid only if the drop is of sufficient height to provide an adequate sample. *See, id.*, Ln. 36-42 (emphasis added). If such contact is made, the drop will close a circuit, enabling a sensor to determine that the drop is of ample size. *See, id.*, Ln. 42-44. In other words, Douglas explicitly states that the inner sleeve 66 is in contact with the skin **only when the lancing is complete and the outer sleeve 24 is retracted**. As such, a person of ordinary skill in the art, upon reading Douglas, would be led in a direction divergent from the path taken by Applicants. Accordingly, the Examiner's proposed modification of Douglas in light of Roe is improper and conflicts with MPEP directives and Federal Judicial standards.

2. There is no teaching or suggestion to combine Douglas with Dosmann.

There is no teaching or suggestion to combine Douglas and Dosmann. The Examiner proposes that if would have been obvious to substitute Douglas' disposable lancet 12, needle 14, capillary tube 18, and test element 30 with Dosmann's hollow lancet 10 for lancing the skin and collecting fluid to improve test time by integrating the lance, harvest and analysis operation as taught by Dosmann. *See* Final Office Action, at 4. Contrary to this allegation, a

person of ordinary skill in the art would not be motivated to modify Douglas to include Dosmann's hollow lancet 10. The hollow lancet 10 taught by Dosmann is unmovable and, thus, has a single position. Specifically, the housing 18 of Dosmann is designed to control the depth of a puncture into a patient's skin by the lance 12 – i.e., the depth of a puncture corresponds to the length of the lance 12 extending out of the housing 18. *See* Dosmann, ¶ [0013]. Douglas' disposable lancet 12, on the other hand, is specifically designed to be moveable – the lancet 12 is adapted to move between retracted and lancing positions. *See* Douglas, FIGS. 1 and 2; Col. 5, Ln. 37-43 and 59-64. As such, a person of ordinary skill in the art would not have an apparent reason or motivation to substitute Douglas' movable lancet 12 with Dosmann's stationary lancet 10, as proposed in the Non-final Office Action. Moreover, this proposed substitution changes the principle of operation of the Douglas reference, as explained below.

Additionally, Dosmann discloses a disposable optical format/integrated lance 10 for lancing the skin, *see* Dosmann, Abstract, whereas Douglas is explicitly directed to a reusable lancing device 10, *see* Douglas, Col. 6, Ln. 57-63. That is, the lancing device disclosed in Douglas is reusable after the disposable lancet 12, capillary tube 18, and test strip 30 are discarded. Thus, the devices disclosed in Dosmann and Douglas have different uses – the lance of Dosmann is designed for a single use, whereas the lancing device of Douglas is designed for repeated, systematic use. Accordingly, there would be no apparent reason or motivation to incorporate Dosmann's disposable lancet 10 into Douglas' reusable lancing device 10, as proposed by the Examiner.

3. The proposed modifications would change the principle of operation of Douglas.

A person of ordinary skill in the art would not be motivated to modify Douglas' end caps 24, 66 to both remain in contact with the skin during the lancing position as taught by Roe because this would change the principle of operation of Douglas. Douglas teaches that the stimulator sleeve 24 (designated by the Examiner as the "outer end cap") depresses a ring of body tissue in surrounding relationship to the incision, causing the incision to bulge while spreading apart the sides of the incision, as seen in FIG. 1. *See* Douglas, Col. 5, Ln. 51-54. The purported advantage to this design is that a drop of body fluid is formed at the open end of the

incision even if the incision is made in a region of the body where the supply of body fluid is relatively low as compared to, for example, the fingertip region. *See, id.*, Ln. 54-58. Modifying Douglas such that the sleeves 24, 66 both remain in contact with the skin during the lancing position, as proposed by the Examiner, would eliminate this feature - i.e., the inner sleeve 66 would press down on the patient's skin and eliminate the bulge of body tissue. Accordingly, the Examiner's proposed modification is improper because it is in direct conflict with the teachings of Douglas, and would change the principle of operation of Douglas' lancing apparatus 10.

A person of ordinary skill in the art would not be motivated to substitute Douglas' disposable lancet with Dosmann's hollow lancet because this would change the principle of operation of Douglas. Douglas unequivocally states that one object of his invention "is to enable a sample of body fluid to be applied to a test strip which is mounted in a lancing device." Douglas, Col. 3, Ln. 24-25. Another object of Douglas' invention is "to provide a device for minimally invasive sampling comprising a reusable sampler and disposable lancet and sample collection device." Douglas achieves these touted objectives with the disposable lancet 12 having an integral capillary tube 18 with a test strip 30 bonded thereto. *See, id.*, FIGS. 1-4; Col. 3, Ln. 64, -Col.4, Ln. 10; Col. 4, Ln. 18-25; Col. 5, Ln. 25-67. This averment is further supported in Douglas' claims, all of which require inclusion of the disposable lancet. Eliminating this feature, as proposed by the Examiner, would change one of the basic principles under which Douglas' lancing device was designed to operate; as such, the Examiner's proposed modification is not sufficient to render Applicants' claims *prima facie* obvious. *See* MPEP 2143.01(VI) and 2145(III); *In re Ratti*, 270 F.2d at 813.

For at least the foregoing reasons, the pending § 103(a) rejections of claims 1-7 and 10-35 are erroneous and should therefore be reversed.

XIII. SUMMARY

For the foregoing reasons, Appellant respectfully solicits the Honorable Board to reverse the Examiner's 35 U.S.C. § 103(a) rejections of claims 1-7 and 10-35 at least upon the grounds noted above.

The fee of $540.00 required by 37 C.F.R. §41.20(b)(2) is submitted herewith.

The Commissioner is hereby authorized to charge Nixon Peabody, P.C. Deposit Account No. 50-4181, Order No. 247079-000090USPX, for any fees that may be inadvertently omitted which may be necessary now or during the pendency of this application, except for payment of the issue fee.

Respectfully submitted,

Date: July 14, 2010

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ENCLOSURES: Appendices IX-XII

IX. APPENDIX - CLAIMS ON APPEAL

1. (PREVIOUSLY PRESENTED) An apparatus for lancing the skin of a test subject, collecting a body fluid sample from the lanced site on the skin of the test subject, the apparatus comprising:

a body having an open end;

a hollow lancet having a tip adapted to puncture skin and to collect a body fluid sample, the interior of the hollow lancet forming a channel for moving a fluid sample from the tip to a reaction area;

a lancing mechanism disposed within the body, the lancing mechanism coupled to the lancet at an end of the lancet opposite the tip, the lancing mechanism being adapted to move the lancet between a retracted position, a lancing position for puncturing the skin of a test subject, and a collection position for collecting the body fluid sample;

an outer end cap having a first end coupled to the open end of the body and a second end for contacting the skin of the test subject, the outer end cap forming a first aperture therein that the tip of the lancet enters when in the lancing position, the outer end cap having a wall extending to the second end thereof; and

an inner end cap disposed within the outer end cap, the inner end cap having a first end coupled to the open end of the body and a second end forming a second aperture therein that the tip of the lancet enters when in the lancing position, the second end being adapted to contact the skin of the test subject when the lancet is in the collecting position, the inner end cap having a wall extending to the second end thereof, the wall of the outer end cap extending farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap,

wherein the second end of the outer end cap and the second end of the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection.

2. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the lancet comprises fused silica.

3. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the lancet has a

polygonal cross-section.

4. (ORIGINAL) The apparatus of claim 1 further comprising a vacuum member for evacuating air from the inner and outer end caps, the vacuum member being adapted to position the skin of the test subject against the second end of the inner end cap.

5. (ORIGINAL) The apparatus of claim 4 wherein the vacuum member comprises a diaphragm.

6. (ORIGINAL) The apparatus of claim 4 wherein the vacuum member comprises bellows.

7. (PREVIOUSLY PRESENTED) The apparatus of claim 1 further comprising:

a light source for illuminating the reaction of the reagent and the analyte in the body fluid sample; and

a light detector for detecting light transmitted through the reaction.

8. (CANCELLED)

9. (CANCELLED)

10. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the lancet has a square or rectangular cross-section.

11. (ORIGINAL) The apparatus of claim 1 wherein the retracted position and the collection position are substantially the same.

12. (PREVIOUSLY PRESENTED) A method for lancing the skin of a test subject and collecting a body fluid sample from the lanced site on the skin of the test subject for determining the concentration of an analyte in the body fluid sample with a lancing and collection device, the lancing and collection device including a hollow lancet having a tip for

puncturing skin, the method comprising the acts of:

placing an outer end cap of the device against the skin of a test subject;

puncturing the skin with the lancet in a lancing position;

positioning the punctured skin against an edge of an inner end cap of the device, the inner end cap being disposed within the outer end cap;

disposing the tip of the lancet a predetermined distance from the skin pulled against the edge of the inner end cap; and

collecting the body fluid sample from the puncture skin with the tip of the lancet in a collection position,

wherein the outer end cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection.

13. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the hollow lancet includes a reaction area with a reagent adapted to produce a colorimetric reaction indicative of the analyte concentration in the sample, the method further comprising the acts of moving the collected body fluid sample from the tip of the lancet to the reaction area via capillary action.

14. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the analyte is glucose.

15. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the body fluid sample is blood.

16. (PREVIOUSLY PRESENTED) The method of claim 13 further comprising the act of measuring a colorimetric reaction.

17. (PREVIOUSLY PRESENTED) The method of claim 16 wherein the act of measuring further comprises the acts of:

illuminating the colorimetric reaction within a hollow, substantially clear lancet with a light source; and

measuring the amount of light transmitted through the colorimetric reaction with a light detector.

18. (PREVIOUSLY PRESENTED) The method of claim 17 further comprising the act of measuring the amount of light transmitted through the lancet to determine the start time of the colorimetric reaction.

19. (PREVIOUSLY PRESENTED) The method of claim 12 wherein the act of positioning further comprising the act of evacuating the air from the inner end cap with a vacuum member of the device.

20. (PREVIOUSLY PRESENTED) The method of claim 12 further including analyzing the body fluid sample for determining the analyte concentration in the body fluid sample while the collected body fluid sample remains in the lancet.

21. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the capillary channel of the hollow lancet has an inlet, and the act of collecting further comprises positioning the inlet of the capillary channel adjacent the lanced skin.

22. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the lancing device includes an end cap, the method further comprising the act of positioning the skin against the end cap for maintaining the skin in a fixed position.

23. (PREVIOUSLY PRESENTED) The method of claim 22 wherein the act of positioning further comprises the act of activating a vacuum member.

24. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the method further comprises the act of maintaining the skin in a fixed position while collecting the body fluid sample.

25. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the capillary

channel contains a reagent for reacting with the analyte in the body fluid sample and producing a colorimetric reaction indicative of the concentration of the analyte in the body fluid sample.

26. (PREVIOUSLY PRESENTED) The method of claim 25 wherein the act of analyzing further comprises the act of optically analyzing the body fluid sample.

27. (PREVIOUSLY PRESENTED) The method of claim 26 wherein the act of optically analyzing comprises the acts of:

illuminating the colorimetric reaction within the hollow lancet with a light source; and

measuring the amount of light transmitted through the colorimetric reaction with a light detector.

28. (PREVIOUSLY PRESENTED) The method of claim 27 further comprising the act of measuring the amount of light transmitted through the lancet to determine the start time of the colorimetric reaction.

29. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the hollow lancet is substantially optically clear.

30. (PREVIOUSLY PRESENTED) The method of claim 29 wherein the hollow lancet has a polygonal cross section.

31. (PREVIOUSLY PRESENTED) The method of claim 29 wherein the hollow lancet has a rectangular cross section.

32. (PREVIOUSLY PRESENTED) The method of claim 29 wherein the hollow lancet has a square section cross section.

33. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the analyte is glucose.

34. (PREVIOUSLY PRESENTED) The method of claim 20 wherein the body fluid sample is blood.

35. (PREVIOUSLY PRESENTED) The apparatus of claim 1 wherein the inner end cap remains entirely disposed within the outer end cap during the retracted position, the lancing position and the collection position.

X. APPENDIX – EVIDENCE

None.

XI. APPENDIX – RELATED PROCEEDINGS

None.

XII. APPENDIX – RELATED APPLICATIONS

None.